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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/196,161	11/20/1998	YOKE MIN SIN	1459-005B	8822

22429 7590 12/16/2005

LOWE HAUPTMAN GILMAN AND BERNER, LLP
1700 DIAGONAL ROAD
SUITE 300 /310
ALEXANDRIA, VA 22314

EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/196,161	SIN ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-46 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-46 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 21, 2005 has been entered.

2. Applicants' amendment filed November 21, 2005 is acknowledged and has been entered. Claims 1-32, 47 and 48 have been canceled. Claim 49 has been amended. Claims 33-46 and 49 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, with the exception of those discussed below.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 33-46 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al 1992 (PNAS USA, July 1992, 89:6363-6367).

The claims are directed to a vaccine for immunizing fish against ciliated ectoparasitic protozoans comprising an effective amount of a fusion protein (GST-iAgI) expressed from a recombinant DNA sequence for immobilization antigen, repeat I of *Ichthyophthiirus multifiliis* wherein said sequence is SEQ ID NO: 1 and

a medium comprising at least one of buffers, antigens, immunostimulants or carriers. The vaccine, when injected into a fish, provides effective protection against white spot disease caused *Ichthyophthiirus multifiliis*. The fusion protein is produced using *E. coli*.

Clark et al discloses the expression of the immobilization antigen (i.e. iAgI); the cDNA encode a protein of 394 amino acids with a tandemly repeated structure characteristic of the i-antigen of other ciliated parasites (abstract). Clark et al discloses that the immobilization antigens of *I. multifiliis* are analogous to free-living ciliates and parasitic protozoa; and "...that transcript levels increase in parallel with the infectivity of the organism bears on the functional role in this system and is consistent with previous observations suggesting that the i-antigens of *Ich* are involved in the development of protective immunity in fish. (p. 6363, col. 2; see also p. 6367, col. 2). The materials and methods disclose how to obtain a recombinant immobilization antigen (p. 6363-6365). Clark et al discloses the entire amino acid sequence as set forth in SEQ ID NO: 1 (see figure 1). Clark et al discloses "on a more applied level, because the i-antigens of *Ich* interact with the immune system of fish, they have potential as protective immunogens and may be of practical use in the treatment of a pathogen with major impact on aquaculture worldwide." (p. 6367, col. 2).

It is noted that the prior art does not specifically recite a medium (buffer, adjuvant, immunostimulant, or carrier). However, it would be inherent that a vaccine composition would comprise a buffer, adjuvant or carrier of some kind, since the art discloses the use of the antigen in a vaccine for protection against disease.

Since the Patent Office does not have the facilities for examining and comparing applicants' vaccine with the vaccine of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed vaccine and the vaccine of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection of claims 33-46 and 49 (previously 1-8 and 24) under 35 U.S.C. § 102(b) as anticipated by Clark et al 1992 (PNAS USA, July, 1992, 89:6363-6367) is maintained. This rejection is maintained for essentially the same reasons as the rejection of claims 1-8 and 24 under this statutory provision, as set forth in the last Office action. Applicants' arguments filed February 7, 2005 have been fully considered but they are not deemed to be persuasive.

Applicants have asserted that Clark et al would not place one skilled in the art in possession of the present invention. Applicants have asserted that the reference fails to disclose or suggest the formation of a vaccine for immunizing fish against ciliated ectoparasitic protozoans. However, it is noted that the claims are directed to products, a composition comprising the immobilization antigen repeat I of *Ichthyophthiirus multifiliis* and a medium (i.e. a buffer), which the prior art discloses. The prior art discloses the claimed composition comprising the antigen (see materials and methods and figure 1) and a buffer (i.e. SDS buffer).

With regard to Applicants' argument that the prior art does not demonstrate the effectiveness of the vaccine, its application in fish, it is noted that the claimed invention is a product and the recitation of vaccine "for immunizing fish against ciliated ectoparasitic protozoans" is viewed as intended use. The recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). It would appear that the composition of Clark et al would achieve this function since the prior art discusses such a function or intended use. The function is inherent.

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)

Applicants have asserted that the fusion protein of the present vaccine is expressed from a recombinant DNA sequence from the immobilization antigen, repeat I of *Ichthyophthiirus multifiliis* and that the overall sequence of the overall recombinant DNA sequence (SEQ. ID No. 1) is different from the sequence of Figure 1 of Clark et al. Hence, the fusion protein used in the present vaccine could not be the same as that of Clark et al. even if the two proteins are both considered to exhibit the same function, i.e., to agglutinate the ciliated protozoan. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., to agglutinate the ciliated protozoan) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With regard to the sequence of SEQ ID NO: 1, it is noted that the entire claimed sequence is set forth in the prior art of Clark et al, see figure 1 and the sequence search result printout that is attached to this office action. Further, the recitation of "is expressed from recombinant DNA..." and other process claim language as recited in claims 37, 42 and 43 are viewed as process limitations. The lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps, which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972) Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product

of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Applicants have asserted that Clark et al fails to provide any description or enablement of how any vaccine could be prepared. However, the claimed invention is a composition, which components are disclosed in the prior art of Clark et al. Further, Clark et al discloses that the that the immobilization antigens are involved in the development of protective immunity in fish as well as the preparation of recombinantly expressed immobilization antigen from the same source as claimed by Applicants. Applicants have not provided any evidence to suggest that the composition of Clarke et al, which has the same components as Applicants' composition, would not function in the same manner as the claimed composition.

The rejection is maintained for the reasons of record. Applicant's arguments filed November 21, 2005 have been fully considered but they are not persuasive. Applicants have asserted that Clark et al does not describe or suggest how the antigen could be produced and that this clearly suggests the unobviousness of the present vaccine composition in and of itself. As previously stated the claims are directed to a product, fusion protein having the immobilization antigen, which the prior art discloses. The claimed vaccine composition comprises a known component, the immobilization antigen. The term vaccine carries little weight absent evidence of structural difference. The recitation of "vaccine" in the claims is viewed as an intended use. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Corning Glass Works, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically

sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. The statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference between the claimed invention and the prior art. If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim.

With regard to Applicants' arguments that the claimed invention is only a portion of the protein of Clark et al, it is noted that the open claim language fails to exclude unrecited steps and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). Applicants have asserted that three levels of enablement are missing in Clarke et al: 1) the isolation of a protein fragment, 2) the preparation of a fusion protein, and 3) the preparation and use of a vaccine against ciliated ectoparasitic protozoans. However, each one of these items relate to the process of preparation of the vaccine, not the vaccine composition itself, which is what Applicants currently claim. Process limitations are not used to determine the patentability of a product, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

5. No claims are allowed.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
December 7, 2005